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| 10/510,953 | 12/02/2005 | Philippe Marliere | 261089US0XPCT | 5311 |

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| EXAMINER | |
|---|---|
| ZEMAN, ROBERT A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1645 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/510,953 | MARLIERE ET AL. | |
| | Examiner | Art Unit | |
| | ROBERT A. ZEMAN | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *31 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *53-71* is/are pending in the application.

4a) Of the above claim(s) *65 and 71* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53,55-64 and 66-70* is/are rejected.

7)☒ Claim(s) *54* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

The amendment filed on 7-31-2009 is acknowledged. Claims 1-52 have been canceled. Claims 53-71 have been added. Newly submitted claims 65 and 71 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the elected invention is drawn to polynucleotides comprising various degrees of sequence identity to SEQ ID NO:1 whereas claims 65 and 71 are drawn to methods of producing a Cyanophage S-2L polypeptide.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 65 and 71 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 53-64 and 66-70 are currently under examination.

***Claim Rejections Withdrawn***

The rejection of claims 1 and 2 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn. Cancellation of said claims has rendered the rejection moot.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "corresponds to SEQ ID NO:1." is withdrawn in light of the cancellation of claim 1.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "high stringency" is withdrawn in light of the cancellation of claim 2.

***Claim Rejections Maintained***

***35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claims 53, 55-64 and 66-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons set forth in previous Office action in the rejection of claims 1 and 2. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

**Applicant argues:**

1. Polynucleotides that have at least 95% or 98% identity (to SEQ ID NO:1)or which hybridize (to SEQ ID NO:1 or its complement) under high stringency conditions are expressly described on page 8 of the specification.

2. The disclosure of a percent identity provides the necessary written description (as set forth in Example 6 and Example 11 of the Written Description Guidelines Rev. 1).

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, contrary to Applicant's assertion, page 8 of the specification does not explicitly disclose any polynucleotides with a given percent identity to SEQ ID NO:1 or that hybridizes to the polynucleotide of SEQ ID NO:1 (or its complement) with the claimed function (allows the heterologous expression of at least one Cyanophage S-2L polypeptide).

With regard to Point 2, the instant claims correspond to claim 3 of Example 6 and claim 2 of Example 11 as set forth in the Written Description Guidelines Rev. 1. As set forth in said Examples said claims (both the instant claims and the exemplary claims) do not provide a correlation between structure (i.e. the sequence) and the claimed function and hence are not properly described. Consequently, the rejected claims are not properly described.

As outlined previously, the specification discloses SEQ ID NO:1 that corresponds to a cyanophage S-2L genome. SEQ ID NO:1 meets the written description provision of 35 USC 112, first paragraph. However, the aforementioned claims are directed to encompass, sequences that have at least 95% or 99% identity to SEQ ID NO:1 and fragments thereof; sequences hybridizing to SEQ ID NO:1 under high stringency; and modified versions of SEQ ID NO:1 all of which encompass corresponding sequences from other species, mutated sequences. allelic variants, splice variants, sequences that have a recited degree of identity (similarity. homology), and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed."* (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO.1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

> Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404. 1405 held that: ...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines Inc.,* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli,* 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood,* 107 F.3d at 1572, 41 USPQ2datl966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel,* 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only SEQ ID NO: 1, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

***35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 53, 55-64 and 66-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Khudyakov et al. (Virology Vol. 88, 1978, pages 8-18 – IDS filed on 10-29-2004) for the reasons set forth in the previous Office action in the rejection of claims 1 and 2.

**Applicant argues:**

1. Khudyakov et al. does not apply to the instant claims as they don't recite the term "corresponds".

2. Khudyakov et al. cannot inherently anticipate the polynucleotide of SEQ ID NO:1 since it is an engineered sequence that contains D-bases.

3. Khudyakov et al. did not disclose or suggest the replace of the D-bases found in the DNA with adenine with the heterologous expression of Cyanophage S-2L genes.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, the rejected claims are drawn to polynucleotides with either a 95% or 99% identity to or hybridize to SEQ ID NO:1 (or its complement). It is deemed, in absence of evidence to the contrary, that the polynucleotide of Khudyakov et al. meets these limitations.

With regard to Point 2, a sequence is an inherent feature of any polynucleotide. Consequently, Khudyakov et al. doesn't need to explicitly disclose the sequence of the disclosed polynucleotide in order to meet the limitations of the instant claims.

With regard to Point 3, the presence of D-bases in a polynucleotide does not preclude is expression in all host cells (see page 16). Moreover, the instant claims merely require that the claimed polynucleotide allows for heterologous expression in a host cell. Since the polynucleotide of Khudyakov et al. would be expressed in the natural hosts of Cyanophage S-2L, it meets the meets the limitation of allowing heterologous expression in a host cell.

As outlined previously, Khudyakov et al. disclose the genome for the cyanophage S-2L. While said sequence differs from SEQ ID NO:1 in that 2, 6 diaminopurine is completely substituted for adenine. Said genome (polynucleotide) is deemed, in absence of evidence to the

contrary, to read on polynucleotides with either a 95% or 99% identity to or hybridize to SEQ ID NO:1 (or its complement).

Since the Patent Office does not have the facilities for examining and comparing applicants' polynucleotides with the polynucleotides of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed vaccine compositions and the vaccine compositions of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

***Conclusion***

Claims 53, 55-64 and 66-70 are rejected.

Claim 54 is objected to as being dependent on a rejected claim.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT A. ZEMAN whose telephone number is (571)272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert A. Zeman/
Primary Examiner, Art Unit 1645
November 16, 2009